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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,945	12/01/2003	Markus Kurz	COTH-P02-514	2847
28120	7590	06/23/2006	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			PANDE, SUCHIRA	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/725,945

Applicant(s)

KURZ ET AL.

Examiner

Suchira Pande

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species:

- a. Species of catalytic proteins (claims 1, 5, 7, 9 are generic)
 - i. Ribonuclease (claim 14)
 - ii. RNA Ligase (claim 15 in part)
 - iii. RNA polymerase (claim 15 in part)
 - iv. Terminal transferase (claim 15 in part)
 - v. Reverse transcriptase (claim 15 in part)
 - vi. tRNA synthetase (claim 15 in part)
 - vii. Deoxyribonuclease (claim 17 in part)
 - viii. Restriction endonuclease (claim 17 in part)
 - ix. DNA Ligase (claim 18 in part)
 - x. Terminal transferase (claim 18 in part)
 - xi. DNA Polymerase (claim 18 in part)
 - xii. Polynucleotide Kinase (claim 18 in part)
 - xiii. Autoproteolytic protein (claims 29-37, 40)
 - xiv. Self- cleaving enzyme (claim 38)
 - xv. Self-splicing enzyme (claim 39)
- b. Species of detection methods (claims 1 and 29 are generic)

Art Unit: 1637

- xvi. An alteration in Electrophoretic mobility (claim 2 in part & claim 30)
- xvii. Column Chromatography (claim 3 in part & claim 31)
- xviii. HPLC (claim 4 in part & claim 32)
- xix. FPLC (claim 4 in part & claim 32)
- xx. Ion exchange column chromatography (claim 4 in part & claim 32)
- xxi. Size exclusion chromatography (claim 4 in part & claim 32)
- c. Species of capture molecule (claim 2 is generic)
 - xxii. Molecule that is specific for affinity tag (claim 7 in part)
 - xxiii. Molecule is antibody (claim 9 in part)
- d. Species of substrate (claims 1, 5, 7 and 9 are generic)
 - xxiv. Protein (claim 11)
 - xxv. Nucleic Acid (claim 12)
 - xxvi. RNA (claims 13-15)
 - xxvii. DNA (claims 16-18)
 - xxviii. Substrate is covalently bonded to said candidate catalytic protein fusion molecule (claim 19)
 - xxix. Substrate is a substrate-nucleic acid conjugate (claim 20)
 - xxx. Substrate is a protein and is linked to the protein portion of said candidate catalytic protein (claim 21 in part)
 - xxxi. Substrate is non covalently associated with said candidate catalytic protein (claim 22 in part)

Art Unit: 1637

- xxxii. Substrate is covalently bonded to a nucleic acid strand hybridized to the nucleic acid portion of said candidate catalytic protein (claim 23)
- e. Species of assays for determining steps
 - xxxiii. Alteration in molecular size (claim 25 in part)
 - xxxiv. Alteration in charge (claim 25 in part)
 - xxxv. Alteration of conformation of the nucleic acid coding sequence of a fragment thereof (claim 25 in part)
 - xxxvi. Determining whether or not the nucleic acid coding sequence or a fragment thereof is bound to said solid support (claim 27)
- f. Species of detecting steps
 - xxxvii. Detecting the nucleic acid coding sequence or a fragment thereof in association with said solid support (claim 26)
 - xxxviii. Detecting the nucleic acid coding sequence or a fragment thereof in said immunoprecipitation complex (claim 28)

The species are independent or distinct because the catalytic proteins such as DNA Ligase and Ribonuclease etc. listed under a) are enzymes that catalyze completely different reactions and have totally different substrate requirements. Likewise detection methods listed under b) are distinct. Electrophoretic mobility is determined using completely different instruments, based on different principles and requires different steps to perform than chromatography. Species of capture molecules listed under c) such as antibody differs from an affinity tag in both structure and function and is recognized in art as such. Proteins, DNA and RNA etc. listed under d) substrates

Art Unit: 1637

are structurally different molecules. Different methods are used in the art to perform the assays listed under e) for e.g. the molecular size is determined using different techniques. Glycerol density centrifugation is used for determining size of native protein while SDS gel is used for determining size of denatured protein. An antibody is used to detect nucleic acid by immunoprecipitation while affinity chromatography can be used to detect nucleic acid in association with solid support.

Thus not only are these species are independent or distinct but to search for them together would be extremely burdensome because separate searches would have to be performed in different databases.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of the categories a. through f. enumerated above, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suchira Pande whose telephone number is 571-272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TERESA STRZELECKA
PATENT EXAMINER

Teresa Strzelecka
6/21/06

Suchira Pande
Examiner
Art Unit 1637